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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,260	08/31/2006	Torsten Michael Reinheimer	052209-0152	4751

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FOLEY AND LARDNER LLP
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WASHINGTON, DC 20007

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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02/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,260	Applicant(s) REINHEIMER ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-19 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060718</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. The abstract of the disclosure is objected to because of the use of the legal phraseology “said”. Also, the Abstract should recite more specifically the diseases intended to be treated by the invention. Correction is required. See MPEP § 608.01(b).

2. Claims 9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 9, line 3, and claim 18, line 2, “the foetus” should be changed to “a foetus” in order to avoid issues of antecedent basis.

3. Applicant is advised that should claims 1 and 10 be found allowable, claims 8 and 17, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Independent claims 1 and 10 recite diseases relating to oxytocin-induced vascular contractility. By definition, “vascular contractility” must occur in a vessel. Dependent claims 8 and 17 recite that the oxytocin-induced vascular contractility occurs in heart, kidney, brain, thymus, pancreas “or any other vessels”, i.e. that it occurs in a vessel. Accordingly, claims 8 and 17 are identical in scope with claims 1 and 10, respectively.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-3, 5-12, 14, 16, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 94/25485. The WO Patent Application '485 teaches nonapeptide oxytocin antagonists used to inhibit uterine contractions caused by bodily oxytocin, to inhibit preterm labor, and to treat hypertension. See, e.g., the Abstract; page 4, lines 24-28; page 8, lines 9-22; and page 9, lines 5-20. With respect to instant claims 6 and 9, an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

6. Claims 1-13, 16, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Goodwin et al article (Obstet. Gynecol., Vol. 88, pages 331-336). The Goodwin et al article teaches atosiban in the form of a bolus and an infusion, in various amounts and administration rates. Atosiban is taught to be a competitive inhibitor of oxytocin, i.e. an oxytocin antagonist, and is used to diminish preterm uterine activity in humans. See, e.g., the Abstract and page 331, column 2, first paragraph. With respect to instant claims 1-9, note that intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art. Because the Goodwin et al article characterizes atosiban as an oxytocin antagonist, and because the Goodwin et al article describes atosiban as acting on the uterus, the preterm labor treated by the Goodwin et al article is deemed inherently to constitute a disease relating to oxytocin-induced vascular contractility to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the compositions and methods of the Goodwin et al article and Applicants' claimed compositions and methods to shift the burden to Applicants to provide evidence that the claimed compositions and methods are unobviously different than those of the Goodwin et al article.

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7. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest the use of oxytocin antagonists to treat pregnancy-related hypertension, preeclampsia, IUGR, fetal hypoperfusion, PIH, toxemia, HELLP syndrome, or eclampsia. The bulk of the prior art of record concerned with oxytocin antagonists is directed towards their use to treat preterm labor, and especially to prevent contractions in the uterus. Such specific usage does not anticipate or render obvious the specific diseases recited in claims 15 and 18. While the prior art of record, e.g., the WO Patent Application 94/25485, teaches the use of oxytocin antagonists to treat hypertension in general, such a generalized teaching does not render obvious treatment of pregnancy-related hypertension specifically. Applicants' Example 1 and Figure 1 do show that oxytocin antagonists can be used in vivo to reduce hypertension in pregnant rats.

Goetz et al (U.S. Patent No. 5,095,003) is cited as art of interest, being essentially duplicative of the references applied above.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal

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communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
February 26, 2009